

Serial No. 09/763,994

REMARKS

This paper is responsive to the Office Action mailed February 18, 2004. Claims 32-36, and 38 remain in this application. Claims 37, and 39-47 have been cancelled. Applicants request that Claim 43 be rejoined once allowable subject matter is found. Claim 32 has been amended, support for which may be found in the specification, for example, at Page 14, Line 12. No new matter has been introduced into the claims. Reconsideration of the subject application in light of the amendments herein and the remarks that follow is respectfully requested.

The Pending Claims are Fully Enabled for Purposes of 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 32 and 38 because the specification, while being enabling for a salt of an hLTBP-3 polypeptide, allegedly does not reasonably provide enablement for a pharmaceutically acceptable salt of an hLTBP-3 polypeptide. Applicants traverse this rejection because a specification need not describe what is well known in the art. A person of ordinary skill in the art would know what a pharmaceutically acceptable salt would be. To further prosecution, however, Applicants have amended claim 32, but Applicants do not intend to be limited by any salt or other formulation. Therefore, this rejection is now moot.

In addition, the Examiner argues that the specification is nonenabling for the modulation of TGF-beta activity with the exogenous administration of hLTBP-3.

Under controlling Federal Circuit case law, it is axiomatic that a specification is presumed to be enabling unless the Examiner provides acceptable objective evidence or sound scientific reasoning showing that it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. In *In re Cortright*, 49 USPQ2d 1464, 1466 (Fed. Cir. 1999), the court stated that the PTO cannot make a 112, first paragraph, rejection for lack of enablement, unless the PTO "has reason to doubt the objective truth of the statements contained in the written description." See also, *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971) (A specification disclosure complies with the enablement requirement, "unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.") Thus, under *Cortright* and *Marzocchi*, the claims in an application are presumed to be enabled unless proven otherwise.

Serial No. 09/763,994

Applicants direct the Examiner's attention to Example 10, Page 49, which provides a working example of the effect of hLTBP-3 on TGF-beta production. In the present case, the Examiner has not provided any evidence or arguments addressing what information is missing and/or why a person of ordinary skill in the art could not practice the present invention without undue experimentation.

Finally, the Examiner notes that Claims 40 and 43 achieve opposite results with the administration of identical compounds, and the specification lacks guidance for achieving one result to the exclusion of the other. Applicants have noted an error in the dependency of Claim 40, which should depend from Claim 39 instead of Claim 38. However, Applicants have cancelled Claim 40, which renders the present rejection moot. Claim 43 is presently withdrawn but will be rejoined once allowable subject matter is found. Guidance and working examples for carrying out the method of Claim 43 may be found in Examples 7, 8 and 10 of the specification.

For the above-mentioned reasons, Applicants respectfully request that the lack of enablement rejection be withdrawn.

The Pending Claims Distinctly Claim and Particularly Point Out the Subject Matter Which Applicants Regard as the Invention for Purposes of 35 U.S.C. § 112, Second Paragraph

The Examiner argues that Claims 32-36 and 38 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner argues that the claimed genus is not adequately described because the genus is highly variable, and therefore, the term "hLTBP-3 polypeptide" becomes unclear. Furthermore, the Examiner states that no common functional attributes identify the members of the genus. Applicants respectfully traverse this rejection.

Applicants direct the Examiner's attention to the specification at Page 18, wherein Applicants have provided a table demonstrating the possible amino acid substitutions that may be used in the provided sequences. The key here is that, "[m]odifications of hLTBP-3 polypeptides made in accordance with the Table are generally expected to retain the biological activity of the parent molecule..." (Page 17, Lines 20-22). Furthermore, the functionality of these polypeptides is clear as indicated in the name of the protein—hLTBP-3 stands for human Latent TGF-beta Binding Protein 3. As such, all

Serial No. 09/763,994

members of this genus have the function of binding TGF-beta. Given this limitations, Applicants maintain that the scope of the claims is clear, and respectfully request the Examiner to withdraw this rejection.

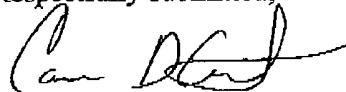
The Pending Claims Meet 35 U.S.C. § 101 Requirements

The Examiner rejected Claims 32-36, and 38 under 35 U.S.C. §101 because the claimed invention is allegedly directed to nonstatutory subject matter. The Examiner suggests amending the claims to "indicate the hand of the inventor" by inserting either "isolated" or "purified." Applicants have amended the claims accordingly, support for which can be found in the specification at Page 14, Line 12. Applicants respectfully request that this rejection be withdrawn.

SUMMARY AND CONCLUSION

In view of the remarks and amendments enclosed and provided herein above, it is respectfully submitted that Examiner's rejections have been overcome. Applicants request reconsideration and withdrawal of the rejections. If Examiner feels that a telephone conversation with Applicants' attorney would be helpful in expediting prosecution of this case, the Examiner is invited to call Applicants' attorney.

Respectfully submitted,



Caren D. Geppert
Attorney for Applicants
Registration No. 54,117
Phone: 317-651-4215

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

July 19, 2004